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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,333	09/29/2005	Kenji Motokawa	082368-002100US	2713

20350 7590 06/17/2009

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,333	MOTOKAWA ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/2005 and 4/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2009 has been entered.

Response to Amendment

The amendments to the claims filed April 13, 2009 have been acknowledged and entered. Claims 1 and 2 are currently amended.

Status of the Claims

Claims 1-3, 5 and 9-12 are pending and under examination. Claims 4 and 6-8 have been canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-3, 5 and 8-12 under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al. (US Patent 5,770,211) in view of Motokawa et al. (Microbiology and Immunology, 1996, Vol. 40, No. 6, pages 425-433) **is maintained for claims 2, 9-10 and 12 and withdrawn for claims 1, 3, 5 and 11.**.

Response to Arguments

Applicant's arguments filed April 13, 2009 have been fully considered but they are not persuasive. Applicants argue "The Examiner has not shown that one of skill in the art would reasonable expect a vaccine as recited in the present claims to be effective for prophylactic treatment or conferring cellular immunity in a cat." Wasmoen teaches the composition is suitable for vaccines as indicated in claims 4 and 6 wherein the vaccine comprises the N gene. Applicants argue "Neither Wasmoen nor Motokawa suggest use of a Type 1 FIPV N protein for use as a vaccine." Wasmoen teaches a vaccine comprising the genes for the N protein of FIPV (column 1, lines 63-66). Motokawa teaches FIPV I is more prevalent in cats and uses the KU-2 stain which is type I FIPV (page 426, Material and Methods). Applicants argue "The FIPV vaccine described by Wasmoen is not widely acknowledged in later reports in the field, while the difficulty with designing N-protein based FIPV vaccines continued to be described." Applicants provided an example of recent article by German et al. (2004) to provide evidence that a feline coronavirus vaccine has been unsuccessful. This is not found persuasive because German et al. discusses feline coronavirus vaccines in general and only references a recombinant vaccinia virus expressing the S protein of avirulent feline coronavirus.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5 and 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 2 are drawn to a genus of polypeptides comprising any polypeptide that is at least 95% identical to SEQ ID NO: 2, wherein 1-15 amino acids are substituted, deleted, added and/or inserted. Claims 5 and 9-12 read on a vaccine comprising the polypeptide or methods for the use of polypeptides that are at least 95% identical to SEQ ID NO: 2 for the purpose of prophylactic treatment against FIPV. These claims therefore implicitly require that the polypeptides are capable of antigenicity in vaccinated subjects.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... reduction to drawings .... or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

It is also noted that even the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in the performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997) (citing Smyth for support). Thus, when a claim covers a genus of inventions, the specification must provide sufficient written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed, or provided a function and a structure correlating with that function. However, in situations where the operability of other species than those provided is uncertain, additional support may be required over that which would be required where greater certainty is present.

In the present case, the Applicant has provided claims drawn to a genus of polypeptides having a sequence of at least 95% identity to SEQ ID NO: 2, wherein the polypeptides confer cellular immunity against FIPV. The application also provides no examples of proteins, other than the sequence itself, which shares at least 95% identity to SEQ ID NO: 2, including no examples of the N protein used in a vaccine formulation directed against FIPV, or the specific substitutions, deletions, additions or variants of SEQ ID NO: 2. The application therefore fails to identify any variants of SEQ ID NO: 2 that provide immunity against FIVP in a subject.

The teachings in the art indicate that single amino acid changes can alter the antigenicity of the protein. See e.g., Riffkin et al., Gene 167:279-83, abstract (indicating that a single amino acid change between two proteins determines the ability of such proteins to bind to an antibody). The art also indicates that amino acid substitutions outside of an antigenic site in a protein may affect that ability of the protein to react with antibodies targeting the protein. Abaza et al., J Prot Chem 11:433-44. Thus, the art indicates that there is uncertainty in the ability of mutant versions of proteins to interact with antibodies directed against the original protein.

In view of the uncertainty in ability of mutants of SEQ ID NO: 2 to perform the required functions (antibodies that can bind to proteins comprising the amino acid sequence encoded by the polypeptide), and the lack of any disclosure of other species than SEQ ID NO: 2 that perform such functions, the disclosure fails to provide adequate support for the claimed genus.

It is noted that descriptive support may also be provided by the combination of a function with a correlating non-functional characteristic. However, the Applicant has not demonstrated that sharing 95% identity to SEQ ID NO: 2 is a structural characteristic that correlates with the ability of a protein to bind either of the indicated groups of antibodies.

The claims are therefore rejected as lacking adequate descriptive support for the claimed genus of polypeptide comprising mutants of SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **2 and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Motokawa et al. (Microbiology and Immunology, 1996, Vol. 40, No. 6, pages 425-433).

The claimed invention is of record.

Motokawa et al. (hereinafter Motokawa) teaches the SEQ ID NO: 1 and SEQ ID NO: 2 from the instant claimed invention (pages 428-429, Figures 2 and 3, strain KU-2). Motokawa teaches a composition comprising the N protein of FIPV and SEQ ID NO: 1 and SEQ ID NO: 2, therefore teaching the composition of claims 1 and 2 of the instant invention. A vaccine is the intended use of the composition of claims 1 and 2. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al. (US Patent 5,770,211) in view of Motokawa et al. (Microbiology and

Immunology, 1996, Vol. 40, No. 6, pages 425-433) and Duphar International Research (EP 0 411 684 A2, 1991) (see IDS filed 9/29/2005).

The claimed invention is of record in the action filed 11/20/2008.

Wasmoen et al. (hereinafter Wasmoen) teaches a feline infectious peritonitis virus (FIPV) vaccine comprising the N protein of FIPV (column 1, lines 65-67 and column 2, lines 1-4). Wasmoen teaches the vaccine is prepared by creating a recombinant poxvirus containing the N protein of FIPV or immunogenic fragments (column 2, lines 45-48). Wasmoen teaches administering the vaccine to a feline (column 2, lines 5-8). While Wasmoen teaches the use of the nucleic acids encoding the proteins in a DNA vaccine, the reference does not specifically teach the use of a protein based vaccine comprising the proteins. Wasmoen does not teach SEQ ID NO: 1 and SEQ ID NO: 2.

Motokawa et al. (hereinafter Motokawa) teaches the SEQ ID NO: 1 and SEQ ID NO: 2 from the instant claimed invention (page 428-429, strain KU-2). Motokawa teaches both FIPV types I and II cause infectious peritonitis in cats, however the pathogenicity of type II FIPV is greater than that of type I FIPV (page 425, 2nd column). Motokawa teaches the prevalence of FIPV type I is higher and about 70% of feline cases are due to type I (page 425, 2nd column).

Duphar International Research (hereinafter Duphar) teaches a vaccine against FIPV comprising the amino acid sequence of the N protein (column 1, lines 7-13).

Since Wasmoen teaches a vaccine comprising the N protein of FIPV, Motokawa teaches a composition comprising SEQ ID NO: 1 and SEQ ID NO: 2, and Duphar teaches a vaccine comprising the N protein of FIPV, it would have been obvious to a person of ordinary skill in the art to formulate a vaccine against FIPV with the N protein of SEQ ID NO: 1 and SEQ ID NO: 2.

A person of ordinary skill in the art would have reasonably expected success because Wasmoen teaches how to make the vaccine comprising FIP immunogens and Duphar teaches using the amino acid sequence of the N protein in the vaccine against FIPV. Motokawa also teaches FIPV I is more prevalent in cats therefore it would have been obvious to a person of ordinary skill in the art to make a vaccine with the strain that is more common.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Olsen (US Patent 5,460,815) teaches a vaccine against FIPV comprising FIP immunogens.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M, T, Th, F 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

June 4, 2009